

COLORADO STATE BOARD OF PHARMACY

April 17, 2008

Minutes

The Colorado State Board of Pharmacy meeting was convened by President E. Katherine Edelblut, R.Ph., at approximately 8:35 a.m. on Thursday, April 17, 2008 at 1560 Broadway, Conference Room 1550, Denver, CO. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., E. Katherine Edelblut, R.Ph.; Leonard Hierath, P.E., Paul Limberis, R.Ph.; and Mitchell P. Sprier, R.Ph.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chief Inspector, Chris Gassen, R.Ph.; Inspectors Billie Marseilles, R.Ph.; Susan Martin, R.Ph.; and Mark O'Neill, R.Ph.; and Aaron Acker, Specialist, Office of Expedited Settlement. Also present was Jo Kaye, Assistant Attorney General, to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the March 20, 2008 meeting as amended.

ADDITIONS TO THE AGENDA

Ms. Anderson advised the Board of the following additions to the agenda:

- Initial Decision in Lawrence B. Kurtz matter
- Additional applicant for REC Committee
- Discussion of Rule 21.00.00, Compounding

APPEARANCES

Jennifer Trainer, SNS Coordinator, Division of Emergency Preparedness and Response, Colorado Department of Public Health and Environment presented information regarding the Colorado Strategic National Stockpile and CHEMPACK to the members.

HEARINGS

The Board conducted a public hearing concerning additions of or amendments to the following regulations: 5.01.31, 15.01.11, 15.01.12, 15.09.11, 15.09.14, and 22.00.00 (3 CCR, 719-1). The hearing began at 9:40 a.m. and was held in Conference room 1550 at 1560 Broadway, Denver, Colorado. The Board discussed all proposed changes to the rules then adopted the rules as proposed.

REPORTS

President's Remarks

Ms. Edelblut thanked the Board members who had participated in the Special Meeting on April 16, 2008 to discuss compounding.

Program Director's Report

Ms. Anderson reminded the Board members that they would be visiting University Hospital and the School of Pharmacy at the University of Colorado Denver at their May meeting.

The members then discussed the appointment of three new members to the Rehabilitation Evaluation Committee. After due consideration, the Board voted to appoint Jon Richard, Psy,D., Gerald Young, RPh, and Janet Bender, RPh, to the Committee.

The Board discussed proposed Board Policy 40-6. In addition, Ms. Anderson passed out a request from Becky Rabbitt, PharmD from the institute for the Certification of Pharmacy Technicians (ICPT) requesting an appearance before the Board. After due consideration, the Board declined Dr. Rabbitt's request and voted to approve policy 40-6.

The member then discussed proposed amendments to Rule 3.04.00 regarding the Colorado Cancer Drug Repository Program. After due consideration, the Board moved these rules to hearing.

The members then discussed the proposed meeting dates for 2009 and 2010 and approved them.

Ms. Anderson then requested and the Board provided the goals for the Pharmacy Technician Taskforce. Rich Doyle, Paul Limberis, Jeannine Dickerhofe, and Mitchell Spreier volunteered to be part of that committee. In addition, the members made suggestions for the individuals that should serve on that committee.

Ms. Anderson advised the Board that the nuclear taskforce had completed its work and proposed amendments to the rules would be brought forth at an upcoming meeting.

Ms. Anderson then passed out a proposal for the Board staff to handle cases which arise from pharmacy's non-compliance with the data submission requirements of the Electronic Prescription Drug Monitoring Program (PDMP). After due consideration, the Board approved the following:

- 1) In situations in which the pharmacy has failed to register with the PDMP and/or submit data within 30 days of becoming registered with the Colorado State Board of Pharmacy or within 30 days of being notified that registration and data submission is required, Board staff will initiate a complaint against the pharmacy's registration in the name of the Board. If the pharmacy should come into compliance and submit data for two consecutive reporting periods, Board staff will dismiss the complaint with a confidential letter of concern. Should the pharmacy fail to come into compliance, Board staff will refer the case to the Office of Expedited Settlement (ESP) for disciplinary proceedings. The terms to be offered to the pharmacy are a stipulation with a non-negotiable

\$5000 fine and agreement to comply with future PDMP submission. In lieu of this, the pharmacy may relinquish its registration.

- 2) In the situations in which pharmacies fail to submit data to the PDMP for two consecutive reporting periods, Board staff will send a letter directing the pharmacy to come into compliance within 14 days and to remain compliant in the future. If the pharmacy does not come into compliance within 14 days, Board staff will initiate a complaint against the pharmacy in the name of the Board. After the initiation of the complaint, if the pharmacy comes into compliance within 30 days and remains so for two consecutive reporting periods, Board staff will dismiss the complaint with a confidential letter of concern. If the pharmacy fails to come into compliance within 30 days, Board staff will refer the case to the Office of Expedited Settlement (ESP) for disciplinary proceedings. The terms to be offered to the pharmacy are a stipulation with a non-negotiable \$5000 fine and agreement to comply with future PDMP submission. In lieu of this, the pharmacy may relinquish its registration. If after receipt of the letter directing compliance within 14 days, the pharmacy complies and remains so, no action will be taken. If, however, the pharmacy initially comes into compliance but fails to remain so, Board staff will initiate a complaint against the registrant. If the pharmacy then comes into compliance within 30 days and remains so for two consecutive reporting periods, Board staff will dismiss the complaint with a confidential letter of concern. If the pharmacy fails to come into compliance within 30 days, Board staff will refer the case to the Office of Expedited Settlement (ESP) for disciplinary proceedings. The terms to be offered to the pharmacy are a stipulation with a non-negotiable \$5000 fine and agreement to comply with future PDMP submission. In lieu of this, the pharmacy may relinquish its registration.

Colorado Pharmacists Society (CPS) – Rich Doyle, RPh

Val Kalnins reported on behalf of Rich Doyle that the Colorado Pharmacists Society's next CE program is the 2008 CPS Annual Summer Meeting at the Copper Mountain Conference Center on June 13-14, 2008. Ten hours of ACPE approved education will be provided. The Annual Summer Meeting awards ceremony will include the installation of Benita Rumold as the 2008-2009 CPS President.

The Colorado Pharmacists Society has partnered with the 9 Health Fair on April 12-20, 2008, and has helped organizers get pharmacist volunteers for over 40 sites throughout Colorado. A variety of tools have been developed and posted on the website. These tools include pdf files that can be downloaded, printed and distributed as handouts by the volunteers to increase their level of comfort in discussing issues from asthma, to weight management and smoking cessation.

The Colorado Pharmacists Society, in cooperation with the Colorado Pharmacy Coalition, has identified fifteen volunteers to serve on an immunization task force that will review the current rules and may suggest changes to address the concerns of the task force participants. The date of the first meeting will be announced within the next few days.

Governor's Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

Paul Limberis reported that the GEEERC met in early April. A presentation was given regarding The Colorado Homeland Security Strategy. Three areas were identified by the current administration as priorities:

1. Conducting an audit on the grants administration program to identify any inconsistencies and make sure that the grants are administered correctly.
2. Making the State Homeland Security Strategy visible at the regional level.
3. Adjusting the organizational structure to more effectively engage the regions..

Colorado Homeland Security will now be aligning its strategy with the national strategy and work on the “capabilities based preparedness plan”. This includes prevention, protection, response, and recovery. It will tie training exercises into the strategy at the regional level.

A presentation was made by Scott Lee, the Federal Region 8 Regional Emergency Coordinator (REC). The RECs serve as liaisons with the Federal Government and the states. These are extenders to the Health Departments. They work to prevent, prepare for, respond to and recover from acts of bioterrorism and other public health emergencies, including infectious disease. A most recent example was their coordination and help with the salmonella incident in Alamosa, CO.

Chris Lindley from the Colorado Department of Public Health and Environment provided an update on the Alamosa water situation. Three hundred and seventy two cases of Salmonella were reported in individuals aged 3 weeks to 87 years old, including infants that received formula made with tap water. Denver Water responded with help to provide the hyperchlorination of the water system. This was performed March 25-26, 2008. The GEEERC was not activated as it was determined that this was an emergency management systems response and less a public health response.

Intern & School Relations –Jeannine Dickerhofe, RPh

Cathy Jarvis from the School of Pharmacy at the University of Colorado Denver reported that the Board would hold both its August and September 2008 meetings at the pharmacy school. She reported that the school had 1200 applications for the 2008-2009 school year. From these applications, 269 interviews were conducted for 155 openings in the school. She also reported that for future classes, the number of prerequisites required to be completed prior to enrollment in the school would be increased to 90 hours.

Legislation - Jeannine Dickerhofe, RPh.

The three bills affecting pharmacy introduced in the legislative report during the January board of pharmacy meeting are in various committees and their status is as follows:

- a) HB 1062 – Includes a Drug Therapy Management component in any program administered by the state department.
Signed by the Governor
- b) HB 1032 – Change in payments to pharmacies
Now in HHS Committee
- c) SB 90 Mail Order Bill - Allow Medicaid patients to receive prescriptions through the mail
Now in House HHS Committee
- d) SB 190 – requires that pharmacists serving long term care facilities and assisted living facilities accept returned drugs and mandates that these drugs be redispensed.

This bill passed out of the Senate Health and Human Services Committee on a 4-3 vote and passed out of the full Senate. It will be heard in the House HHS committee in the next few days.

Rules – Rich Doyle

None

Inspectors

None

OLD BUSINESS

DIT Healthcare Distribution, Inc., WHO Applicant

The Board considered a memorandum from Chief Inspector Chris Gassen regarding this application.

After due consideration, the Board approved the application.

NEW BUSINESS

Complaints

Aerocare Pharmacy, OSP 5396

2008-2556

After due consideration of the available information, the Board voted to refer the case for discipline.

Bob's Pharmacy and Diabetic Supplies, LLC, OSP 5702 **2008-2560**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Donald J. Bond, RPh 13569 **2008-2126**

A motion was made, seconded, and carried to dismiss the case as being without merit.

College Pharmacy, PDO 24-38 **2008-2170**

Mitchell Spreier, RPh, recused.

A motion was made, seconded, and carried to dismiss the case as being without merit.

Geriatric Services of America, OSP 5609 **2008-2592**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Healix Infusion Therapy, OSP 5659 **2008-2597**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

IV Solutions of Lubbock, OSP 5400 **2008-2604**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

McCully Snyder Pharmacy, Inc./Custommeds, OSP 5666 **2008-2629**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Med 4 Home Pharmacy #6050, OSP 5101 **2008-2474**

After due consideration of the available information, the Board voted to refer the case for discipline.

Med Mart Pharmacy, OSP 5229 **2008-2630**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Med-Care Pharmacy, OSP 5633 **2008-2631**

After due consideration of the available information, the Board voted to refer the case for discipline.

Medi-Physics, Inc., OSP 5431 **2008-2653**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Medical Arts Pharmacy Services, Inc. , OSP 5693 **2008-2654**

After due consideration of the available information, the Board voted to refer the case for discipline.

Dominique Minjarez, IN 2002891 **2008-2055**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Camille N. Pacheco-Gach, RPh 13322

2008-2374

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Julio E. Pazmino, RPh 17246

2008-2054

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

PharmaCare Specialty Pharmacy #2751, OSP 5451

2008-2676

After due consideration of the available information, the Board voted to refer the case for discipline.

RxC Acquisition Company, OSP 5286

2008-2683

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Specialty Pharmaceutical Services, WHO 7354

2008-2437

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Steven's Pharmacy, OSP 5387

2008-2688

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

Vicki L. Stoeckley, RPh 16234

2008-2313

A motion was made, seconded, and carried to dismiss the case as being without merit.

The Board then voted to send a letter to Albertson's/Sav-On District Office requesting a response within 30 days.

US Compounding, Inc., OSP 5611

2008-2689

After due consideration of the available information, the Board voted to refer the case for discipline.

Watson Pharma, Inc., Unregistered

2008-2107

A motion was made, seconded, and carried to dismiss the case as being without merit and send a Letter of Guidance to the facility.

Lawrence B. Kurtz , RPh 9870

The Board considered the Initial Decision issued on February 29, 2008 in Board Case Number 2006-0773. After due consideration, the Board voted to adopt the Initial Decision of ALJ Schulman in its entirety and approved terms for a Final Agency Order.

LICENSING

Other Outlets, New

The Board approved the registration of 1 new outlet.

Prescription Drug Outlets, New (In-State)

The Board approved the registrations of 2 new in-state outlets.

Prescription Drug Outlets, New (Out-of-State)

The Board approved the registrations of 3 new out-of-state outlets.

Wholesalers

The Board approved the registrations of 7 Out-of-State Wholesalers.

The Board approved the registration of 1 In-State Wholesaler registration.

Manufacturers

The Board did not approve any Manufacturer registrations.

Limited Licenses

The Board did not approve any Limited License registrations.

Licensure by Examination

The Board ratified the licensure of 4 applicants for licensure by examination.

Licensure by License Transfer

The Board ratified the licensure of 6 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

Licensure Issues

Pharmacy Intern Licensure Issues

Mitchell J. Daley, Pharmacy Intern Applicant

The Board voted to approve the application.

Prescription Drug Outlet Licensure Issues

Coram Alternate Site Services, Inc., PDO 37-24

After due consideration of the available information, the Board approved the modified remodel plans.

MISCELLANEOUS

Correspondence, etc.

NABP Supports White House's Commitment to End Illegal Internet Drug Sales

The Board reviewed and noted the information.

EXECUTIVE SESSION

Board President E. Katherine Edelblut moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (III) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-4-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

Case Status Reports

The Board discussed case 2008-1638 and provided settlement information to the Office of Expedited Settlement.

The Board read and discussed the April 16, 2008 case status report from Mr. Acker.

The Board read and discussed the April 17, 2008 case status report from Ms. Kaye.

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

Open Session

E. Katherine Edelblut, Mitchell Spreier, Rich Doyle, and Paul Limberis continued discussing the proposed compounding rules.

ADJOURNMENT

The Board adjourned at 4:10 p.m.

Approved by E. Katherine Edelblut, RPh, President

Date: May 15, 2008

Attestation:

Pursuant to § 24-6-402(2)(d.5)(I)(B), C.R.S. , as Board President, I attest that the executive session of the Colorado Board of Pharmacy meeting held on April 17, 2008, was confided to the topics authorized for discussion pursuant to 24-6-402(3)(a)(II), 24-6-402(3)(a)(III), C.R.S.

Approved by E. Katherine Edelblut, RPh, President

Date: May 15, 2008

Pursuant to § 24-6-402(2)(d.5)(I)(B), C.R.S. , as counsel for the Board, I attest that it is my opinion that all matters discussed during the executive session of the Colorado Board of Pharmacy meeting held on April 17, 2008, constituted attorney-client communications and the contents of attorney-client discussions are not reflected within these minutes.

Approved by Jo Kaye, Assistant Attorney General

Date: May 15, 2008